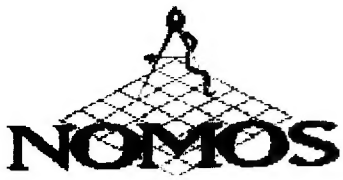
K013036

DEC 0 7 2001



Section 2 – 510(k) Summary

Summary of Safety and Effectiveness
NOMOS Motorized CRANE® II

Pursuant to Section 513(i) of the Federal Food, Drug, and Cosmetic Act

A. General Information:

Classification Name: Medical charged-particle radiation therapy system accessory (Sec. 892.5050)

Common/Usual Name: Caliper

Trade/Proprietary Name: NOMOS Motorized CRANE® II

Applicant's Name and Address: Francis X. Dobscha
Director of Quality

NOMOS Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

Phone: 724-934-8242
FAX: 724-934-5488

B. Name of predicate device: NOMOS CRANE II (K991966)

C. Classification: Class II

D. Performance Standards: None established

E. Intended Use and Device Description:

Intended Use:

The NOMOS Motorized CRANE II is intended to be used as an accessory to powered radiation therapy patient support tables. The NOMOS Motorized CRANE II verifies and describes, via a set of Z and X coordinates, the set-up of the table/patient prior to treatment.

Device Description:

The NOMOS Motorized CRANE II is a powered version of the manual NOMOS CRANE II. It is an accessory to radiation therapy patient support tables.

Like the NOMOS CRANE II, the Motorized CRANE II attaches to the stationary base of the treatment table through a permanently installed interface plate and clamps to the accessory rails of the moveable table top. The Motorized CRANE II can be removed from the treatment table when its use is not required, leaving only the interface plate remaining on the stationary base of the treatment table.

The Motorized CRANE II uses precision ball screw drive positioning mechanisms (one for the Z-axis and one for the X-axis) to position the table top relative to the stationary base of the treatment table.

While these positioning mechanisms retain the small hand cranks employed in the predicate CRANE II to allow manual operation when needed, the primary drive force is provided by two electric motors – one for each axis of movement. These motors are software-controlled, and operator interface is provided through two touch screen control panels – one located on the device and one remote panel that can be placed in the treatment control room.

The control panels display the position of the patient treatment table, and allow the operator to specify and initiate movement in the Z and X axes. Using the NOMOS CRANE II, the operator can move the treatment table over a range of 300 mm in each axis. When attached to a treatment table loaded to a maximum weight of 300 pounds, the NOMOS Motorized Crane II is capable of +/- 0.1 mm accuracy in the Z-axis, and +/- 0.4 mm accuracy in the X-axis.

The Motorized CRANE II retains the battery-powered digital scales from the Crane II as an independent means of position verification.

F. Summary of Substantial Equivalence

Indications:

The indications for the NOMOS Motorized CRANE II are the same as for the predicate device, the NOMOS CRANE II; that is, to verify and describe the set-up of the table/patient position prior to treatment.

Design:

The design of the NOMOS Motorized CRANE II is equivalent to the NOMOS CRANE II, with the addition of electric drive motors, operator interface displays, and software controls.

Materials:

The materials used in the NOMOS Motorized CRANE II are equivalent to those used in the predicate NOMOS CRANE II.

Manufacturing:

The manufacturing processes used in the production of the NOMOS Motorized CRANE II are equivalent to those used in the manufacture of the predicate NOMOS CRANE II and are performed at the same facility.

Specifications:

The operating specifications of the NOMOS Motorized CRANE II are equivalent to the predicate NOMOS CRANE II, particularly with respect to range of movement and accuracy.

Conclusions:

The addition of electric motors and software controls to the design do not raise any new issues relating to safety and effectiveness. NOMOS thus considers the NOMOS Motorized CRANE II to be substantially equivalent to the predicate device – the NOMOS CRANE II.

Note:

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be legally marketed according to FDA regulations and is not relevant evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, *". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits."* 42 Fed. Reg. 42,520 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Mr. Francis X. Dobscha
Director of Quality
NOMOS Corporation
2591 Wexford Bayne Road
SEWICKLEY PA 15143

Re: K013036
Trade/Device Name: NOMOS Motorized Crane II
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: 90 JAI
Dated: August 21, 2001
Received: September 10, 2001

Dear Mr. Dobscha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: Not Assigned K013036

Device Name: **NOMOS® Motorized CRANE II**

Indications for Use:

The NOMOS Motorized CRANE II is intended to be used as an accessory to powered radiation therapy patient support tables. The NOMOS Motorized CRANE II verifies and describes, via a set of Z and X coordinates, the set-up of the table/patient prior to treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jeyson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013036

Prescription Use ✓ OR Over-The Counter Use ____
(Per 21 CFR 801.109)